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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,310	02/20/2004	Yegor Sinelnikov	TRANS 3.0-055	7812
530 7590 05/25/2007 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER VRETTAKOS, PETER J	
			ART UNIT 3739	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/783,310

Applicant(s)

SINELNIKOV ET AL.

Examiner

Peter J. Vrettakos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4-26-07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,9,10 and 83-92 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,9-10,83-92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 7, 9-10 and 83-92 are pending.

Amendment filed 4/26/07.

The action is final as necessitated by amendment. Prior anticipation rejections are obviated through amendment. Obviousness rejections are newly presented.

Relevant points to this action: the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of ordinary skill in the art is a cardiac surgeon.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 9-10 and 83-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins et al. (6,837,886).

Collins discloses a method of performing cardiac ablation comprising: injecting a contrast medium (col. 14:64-67) for x-ray visualization (col. 16:31-33) of ablation at the pulmonary vein (see figure 22). The device in figure 22 has "opposite proximal and distal directions" presumably both sides/directions with tubes 102 and ports 104 from the analogous embodiment in figure 18. Furthermore, the delineation between the pulmonary vein and the heart chamber is not distinct in normal physiology and across a patient spectrum (consisting of a population of patients) to patentably distinguish the two. In other words, the Office cannot obviate a rejection because a device in one figure lies in one patient at what appears to be the pulmonary vein (and not the adjacent heart chamber). Where would the device lie in a smaller patient with a smaller heart? Quite possibly the device lies in the wall of the heart chamber. The difference between the adjacent wall of the chamber and the pulmonary vein is simply not patentably distinguishable. (This point comes up repeatably for this Examiner in other applications, as well).

Collins' mesh makes obvious the use of a balloon in the same procedure. (This point comes up repeatably for this Examiner in other applications, as well).

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art (a cardiac surgeon) to modify Collins to arrive at the Applicant's claimed method as motivated by the normal desire of artisans to improve upon what is already known (see below).

Claims 7, 9-10 and 83-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Natale (6,764,486).

Natale discloses a method of performing cardiac ablation comprising: injecting a contrast medium (col. 2:55-58) for x-ray visualization of ablation at the pulmonary vein (see figure 2).

Regarding obviousness and the order in which Natale performs injecting fluid medium and ablation, see MPEP § 2144.04 (IV)(c):

Changes in Sequence of Adding Ingredients

Ex parte Rubin, 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render prima facie obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps.). See also In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.).

Furthermore, the delineation between the pulmonary vein and the heart chamber is not distinct in normal physiology and across a patient spectrum (consisting of a population of patients) to patentably distinguish the two. In other words, the Office cannot obviate a rejection because a device in one figure lies in one patient at what appears to be the pulmonary vein (and not the adjacent heart chamber). Where would the device lie in a smaller patient with a smaller heart? Quite possibly the device lies in

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the wall of the heart chamber. The difference between the adjacent wall of the chamber and the pulmonary vein is simply not patentably distinguishable.

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art (a cardiac surgeon) to modify Natale as motivated by the normal desire of artisans to improve upon what is already known (see below).

Claims 83-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Natale or Collins et al.

Claims 83-88 include language toward obvious surgical steps that would be determined through routine experimentation. See MPEP § 2144.05:

II. OPTIMIZATION OF RANGES

A. Optimization Within Prior Art Conditions or Through Routine Experimentation

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be *prima facie* obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Applied to the instant application, one of ordinary skill would have in light of Natale or Collins et al. determined to perform the very basic surgical steps written into claims 83-88.

The section applies regardless of the specific examples (concentration or temperature) used to make the point that optimization of what is already known comes with a normal desire to improve upon what is already known.

Claims 7, 9-10 and 83-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hassett et al. (6,540,744).

Hassett et al. discloses a balloon (20) ablation device (see specifically figure 8) with opposite proximal and distal directions (34 *in figure 8*) that emits contrast media (makes obvious x-ray contrast medium) distally (28 in figure 8 – “ports”; 32 in figure 4 – makes obvious a stylet; col. 8:17-20; col. 9:14-17; col. 9:36-39) in an ablation procedure that makes obvious the Applicant’s claimed method. Also see “withdraw”/retracting step in col. 9:20-26 after the device has been placed properly.

Furthermore, the delineation between the pulmonary vein and the heart chamber is not distinct in normal physiology and across a patient spectrum (consisting of a population of patients) to patentably distinguish the two. In other words, the Office cannot obviate a rejection because a device in one figure lies in one patient at what appears to be the pulmonary vein (and not the adjacent heart chamber). Where would the device lie in a smaller patient with a smaller heart? Quite possibly the device lies in the wall of the heart chamber. The difference between the adjacent wall of the chamber and the pulmonary vein is simply not patentably distinguishable.

See MPEP § 2144.05 arguments above for the inherent motivation to modify Hassett making obvious the Applicant's invention.

Response to Arguments

Applicant's arguments with respect to all claims have been considered but are moot in view of the new ground(s) of rejection.

Note: it is respectfully submitted that the arguments toward the prior art's lack of express disclosure concerning blood carrying medium back toward the ostium of the vein are irrelevant. This claim language merely describes the physiological response that would inherently occur in the patented methods.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pete Vrettakos
May 15, 2007




ROY D. GIBSON
PRIMARY EXAMINER